#20

Board of Governors of the Federal Reserve System, May 6, 1991.
William W. Wiles,
Secretary of the Board.
[FR Doc. 91-11143 Filed 5-9-91; 8:45 am]
BILLING CODE 6210-01-F

Society Corporation, et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than May 31, 1991.

A. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Society Corporation, Cleveland, Ohio; through its subsidiary Green Machine Network Corporation, North Olmsted, Ohio, to engage in providing data processing services nationwide pursuant to § 225.25(b)(7) of the Board's Regulation Y.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Norwest Corporation, Minneapolis, Minnesota, and Norwest Insurance, Inc., Minneapolis, Minnesota; through their subsidiary National Security Insurance Underwriters of Litchfield, Litchfield, Minnesota, to engage in general insurance agency business including the sale of life, accident and health, property, and casualty insurance products pursuant to § 225.25(b)(8)(vii) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, May 6, 1991.
William W. Wiles,
Secretary of the Board.
[FR Doc. 91-11144 Filed 5-9-91; 8:45 am]
BILLING CODE 6210-01-F

Synovus Financial Corporation, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than May 31, 1991.

A. Federal Reserve Bank of Atlanta (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Synovus Financial Corporation, Columbus, Georgia; and TB&C Bancshares, Inc., Columbus, Georgia; to acquire 100 percent of the voting shares of Athens Federal Savings Bank, Athens, Georgia.

B. Federal Reserve Bank of Kansas City (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Emprise Financial Corporation, Wichita, Kansas; and thereby indirectly acquire Emprise Bank, N.A., Hays, Kansas.

Board of Governors of the Federal Reserve System, May 6, 1991.
William W. Wiles,
Secretary of the Board.
[FR Doc. 91-11145 Filed 5-9-91; 8:45 am]
BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91E-0136]

Determination of Regulatory Review Period for Purposes of Patent Extension; Altace™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Altace™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: I. David Wolfson, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical

device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Altace™ (ramipril), which is indicated for the treatment of hypertension. It may be used alone or in combination with thiazide diuretics. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Altace™ (U.S. Patent No. 4,587,258) from Hoechst-Roussel Pharmaceuticals, Inc., and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated April 15, 1991, advised the Patent and Trademark Office that the human drug product had undergone a regulatory review period and that the approval of the active ingredient, ramipril, represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Altace™ is 2,551 days. Of this time, 1,738 days occurred during the testing phase of the regulatory review period, while 813 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: February 5, 1984. The applicant claims January 27, 1984, as the date the investigational new drug (IND) application for Altace™ became effective. However, FDA records indicate that the IND became effective on February 5, 1984.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: November 7, 1988. The applicant claims November 2, 1988, as the date the new drug application (NDA) for Altace™ (NDA 19-901) was initially submitted. However, FDA records indicate that the application was received on November 7, 1988.

3. The date the application was approved: January 28, 1991. FDA has verified the applicant's claim that NDA 19-901 was approved on January 28, 1991.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 632 days of patent extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 9, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 6, 1991, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 3, 1991.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 91-11140 Filed 5-9-91; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Final Review Criteria for Grants for Nurse Anesthetist Education Programs

The Health Resources and Services Administration (HRSA) announces the final review criteria for fiscal year 1991 for Grants for Nurse Anesthetist Education Programs.

Section 831(a) of the Public Health Service Act authorizes grants to public or private nonprofit institutions to cover the costs of:

1. Traineeships for licensed registered nurses to become nurse anesthetists; and

2. Projects to develop and operate programs for the education of nurse anesthetists.

This announcement addresses grants for projects to develop and operate programs for the education of nurse anesthetists.

To be eligible for a grant, an applicant must be a public or private nonprofit institution accredited by an entity or entities designated by the Secretary of Education and must meet such requirements as the Secretary shall by regulation prescribe.

For purposes of this program eligible projects will be limited to proposals for developing and operating new programs. This is in keeping with the intent of Congress that additional nurse anesthetist education programs be created (Senate Report 101-516, p. 55). An application may be submitted for a project at any stage of program development beginning with the planning period but prior to the graduation of a class. Projects which include a planning period must, before the end of the first year of the project, complete the Capability Review required to achieve Preaccreditation Status from the Council on Accreditation of Nurse Anesthesia Educational Programs (AANA Council). Projects for Nurse Anesthetist Programs which have achieved Preaccreditation status from the AANA Council must have students enrolled or accepted for enrollment, to be eligible. Projects for progams which have graduated a class or will be graduating a class before a grant can be awarded are not eligible.

The period of Federal support should not exceed three years.

National Health Objectives for the Year 2000

The PHS is encouraging applicants to submit proposals that address achievement of Healthy People 2000: National Health Promotion and Disease